

REMARKS

Claims 1-60 are pending in the Application, and Claims 24-60 have been withdrawn from consideration. Claims 1-23 are rejected by the Examiner. Applicant hereby cancels Claims 11 and 12 without prejudice conceding to the Examiner's characterizations. Claims 1 and 16 are amended without prejudice and without conceding to the Examiner's characterizations. Reconsideration of the present Application is respectfully requested.

Claim Rejections Pursuant to 35 U.S.C. 112

Claims 15-16 and 18-19 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant traverses this rejection and deems them overcome for at least the following reasons:

Examiner states that "it is not clear what is encompassed by the phrase 'non-solvent/emulsifier.'" Applicant respectfully submits that the phrase "non-solvent/emulsifier" is recognized in the art to be, as an example, compositions that promote the formation and stabilization of emulsions without dissolving one or more other emulsion ingredients.

The present Application uses the phrase non-solvent/emulsifiers in this manner. Some examples of these compounds are given at Paragraph 33 of the present application which states:

The compositions optionally comprise non-solvent/emulsifier ingredients, such as Glyceryl Stearate (and) PEG-100 Stearate, carbopol 980, cyclomethicone NF, glyceryl monostearate, hydroxyethyl cellulose, hydroxypropyl cellulose, isopropyl myristate, methyl paraben NF, mineral oil, oleic acid NF, PEG-100 Stearate, petrolatum, propyl paraben NF, purified water, stearyl alcohol, white petrolatum, and white wax. [emphasis added].

Therefore, Applicant asserts that the claims of the present application particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 16 has also been rejected for "insufficient antecedent basis." Applicant has amended, without prejudice, the typographical error of Claim 16 to provide a proper antecedent basis for the claim limitation.

Applicant respectfully submits that the above 35 U.S.C. §112 second paragraph rejection has been overcome.

Claim Rejections Pursuant to 35 U.S.C. 102

Claims 1-4, 10 and 14-19 stand rejected under 35 U.S.C. §102(b) as being anticipated by Poulsen, U.S. Patent No. 3,934,013 ("Poulsen"). Applicant respectfully traverses these rejections for at least the following reasons:

35 U.S.C. 102(b) recites:

A person shall be entitled to a patent unless – (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

"[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See, MPEP §2131 citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant has amended, without prejudice, Claim 1, on which all of the other pending claims (rejected under §102) directly or indirectly depend, to be limited to penetration enhancers present in a ratio to a total of the (penetration enhancers and solvents and emulsifiers) of at least about 0.90. Poulsen does not teach the ratio of at least about 0.90, which is an element of Applicant's claims.

Thus, Applicant respectfully submits that the above 35 U.S.C. §102(b) rejection has been overcome.

Claim Rejections Pursuant to 35 U.S.C. 103

Claims 1-7 and 10-19 stand rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Poulsen. Additionally, Claims 1-23 stand rejected pursuant to 35 U.S.C. §103(a) as being unpatentable Poulsen “in view of PDR entries of Lidex-Synalar.”

The Examiner alleges that, “It would have been obvious to one skilled in the art at the time the invention was made to employ corticosteriod” and propylene glycol in the particular weight percentages claimed herein and the ranges in the present invention are “taught to be useful in topical formulations by the prior art.”

Applicant traverses these rejections for at least the reasons stated below.

The Examiner fails to make out a prima facie case of obviousness with respect to Claim 1 as amended. First, a prior art reference or combination of such is required to teach or suggest all claim limitations in order to render a claim obvious. Poulsen does not teach or suggest a ratio of penetration enhancers, to (penetration enhancers and solvents and emulsifiers) at all. Much less a ratio of at least about 0.90. The Examiner does not offer any references, including any specific citations from Poulsen, which refer to this ratio or any ranges of ratios that are “useful in topical formulations.” The Examiner can not point to ratios in Poulsen of at least about 0.90 because Poulsen was not aware of the importance of such ratios. Given that Poulsen did not teach or suggest any penetration enhancer ratio, much less one of at least about 0.90, Applicant believes this rejection is overcome.

Additionally, to the extent that Poulsen teaches or suggests increased efficacy, he does so only by increasing the amount of active ingredients (see column 17, lines 60-63, for example) whereas Applicant's claimed ratio does not alter the amount of active ingredients. Unlike Poulsen, the present invention increases potency by altering the inactive ingredients, not the active ingredients.

Note that the claimed ratios of the present invention provide, for example, an unexpectedly high vasoconstrictor score. For example, the average of summed vasoconstrictor score of 85 was the result of a ratio of at least about 0.90 versus an average of summed vasoconstrictor scores of 71 for a ratio of at least about 0.80 (see Table 2, paragraph 26 of the present application).

Further, for reasons stated above, the claims of the present application as currently amended are not taught or suggested by Poulsen with the PDR entries of Lidex-Synalar ("PDR entries"). The ratio of 0.90 is also not taught or suggested by the PDR entries. Thus Applicant respectfully submits that the PDR entries do not teach or suggest all of the claimed elements.

Since neither Poulsen nor the PDR reference, teach or suggest all of the claim limitations of Claim 1 of the present invention as stated herein above, the combination of Poulsen and the PDR reference does not render obvious Claim 1 nor any of its dependent claims in the present Application. Consequently, Applicant traverses the 35 U.S.C. §103(a) rejections and respectfully requests their reconsideration and removal.

Claims 20 to 23, which are independent claims, have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen in view of the PDR entries. Applicant traverses this rejection for at least the following reasons.

Claims 20 to 23 require the claim elements in specific ranges of ratios. Neither Poulsen nor the PDR entries teach all of the claimed elements. For example, Poulsen does not teach the specific claimed ranges of propylene glycol or water and the PDR entries do not teach any ranges of ingredients. The present invention requires specific ranges for greater efficacy and there is no suggestion in the PDR entries to alter the ranges to include Applicant's ranges. Thus, Applicant respectfully submits that this rejection has been overcome.

CONCLUSION


Applicant respectfully submits that the application is in condition for allowance. Applicant does not believe any additional fee is required for this Response and Request for Reconsideration, however, in the event any additional fee is required or any overpayment credit is due, the Commissioner is hereby authorized to charge Deposit Account No. 18-0586.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/037,360 is/are being facsimile transmitted to the United States Patent and Trademark Office, fax number 703 308 4556 on the date shown below.

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